Service Manual

Responder AED Pro *automated external defibrillator*

2023491-201rB

REVISION HISTORY

Part number	Date	Comment
2023491-201 Rev A	August 2006	Initial Release
2023491-201 Rev B	November 2007	Revised for misc. minor updates and new symbols Corrected shock criteria in Defib testing section

IMPORTANT

Read this carefully. It contains information about your safety and the safety of others. Become familiar with the controls and how to use the AED properly before operating the product.

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PATENTS

This device may be covered by the following U.S. and foreign patents:
5,792,190, 5,999,493, 5,402,884, 5,579,919, 5,749,902, 5,645,571, 6,029,085, 5,984,102, 5,919,212, 5,891,172, 5,674,266, 5,700,281, 5,891,173, 5,968,080, 6,263,239, 5,797,969, D402,758, D405,754, 5,909,138, 6,173,203, 6,088,616, 5,897,576, 5,955,956, 6,083,246, 6,064,909, 6,038,473, 5,868,794, 6,115,638, 6,366,809, 5,474,574, 6,246,907, 6,289,243, 6,411,846, 6,480,734, EP00756878
Other U.S. and foreign patents pending.

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LIMITED WARRANTY

The Responder AED Pro Manual and any and all information contained herein do not constitute any warranty as to the Responder AED Pro or any related products in any manner whatsoever. The “Limited Warranty” is shipped with the AED and serves as the sole and exclusive warranty provided by Cardiac Science regarding Responder AED Pro products.

HOW TO REACH US

To order supplies or accessories, contact your representative or distributor. For technical support, contact your local GE customer service.
Please have the serial and model numbers available. The serial and model numbers are located on the back of the Responder AED Pro.

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FOR YOUR NOTES:

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SECTION 1 - SAFETY

OVERVIEW

This section presents safety information to guard against injury to persons and damage to the Responder AED PRO.

Topic	Page #
Safety Alert Definitions	5
Safety Alert Descriptions	6
Symbols Descriptions	8

SAFETY TERMS AND DEFINITIONS

BEFORE OPERATING THE RESPONDER AED Pro

Become familiar with the various safety alerts in this section.

Safety alerts identify potential hazards using symbols and words to explain what could potentially harm you, the patient, or the Responder AED PRO.

SAFETY TERMS AND CONDITIONS

The triangle attention symbol shown below, left, identifies the potential hazard categories. The definition of each category is as follows:

DANGER: This alert identifies hazards that will cause serious personal injury or death.

WARNING: This alert identifies hazards that may cause serious personal injury or death.

CAUTION: This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

PRODUCT REFERENCES

For purposes of retaining simple, clear instructions in this manual, note the product references used. Features, specifications, operating instructions and maintenance common to the Responder AED Pro will be referred to as “AED.”

Features and specifications vary, so please read this manual carefully.

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SAFETY ALERT DESCRIPTIONS

The following is a list of AED safety alerts that appear in this section and throughout this manual. You must read, understand, and heed these safety alerts before attempting to operate the AED.

DANGER: Fire and Explosion Hazard
Do not use the AED in the presence of flammable gases (including concentrated oxygen) to avoid possible explosion or fire hazard.

WARNING: Shock Hazard
Defibrillation shock current flowing through unwanted pathways is potentially a serious electrical shock hazard. To avoid this hazard during defibrillation abide by all of the following:

- Do not touch the patient, unless performance of CPR is indicated
- Do not touch metal objects in contact with the patient
- Keep defibrillation pads and ECG electrodes clear of other pads or metal parts in contact with patient
- Disconnect all non-defibrillator proof equipment from the patient before defibrillation

WARNING: Shock and Possible Equipment Damage
Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock and potential damage to the equipment.

WARNING: Battery is Not Rechargeable
Do not attempt to recharge the battery. Any attempt to recharge the battery may result in an explosion or fire hazard.

WARNING: Shock Hazard
Do not disassemble the AED! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to authorized service personnel.

CAUTION: Temperature/Humidity/Pressure Extremes
Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self-test verifies the impact of extreme environmental conditions on the AED; if the daily self-test determines environmental conditions outside of the AEDs operating parameters, a "SERVICE REQUIRED" alert will be issued to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once. See Section 7 – Technical Data, Parameters, Operation and Standby Conditions.

CAUTION: Lithium Sulfur Dioxide Battery
Pressurized contents: Never recharge, short circuit, puncture, deform, or expose to temperatures above 65°C (149°F). Remove the battery when discharged.

CAUTION: Battery Disposal
Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

CAUTION: Use only Approved Equipment
Using batteries, pads, cables, or optional equipment other than those approved by GE may cause the AED to function improperly during a rescue.

CAUTION: Possible Improper AED Performance
Using pads that are damaged or expired may result in improper AED performance.

CAUTION: Possible Radio Frequency (RF) Susceptibility
RF susceptibility from cellular phones, CB radios and FM 2-way radio may cause incorrect rhythm recognition and subsequent shock advisory. When attempting a rescue using the AED, do not operate wireless radiotelephones within 2 meters of the AED – turn power OFF to the radiotelephone and other like equipment near the incident.

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CAUTION: Possible Interference with Implanted Pacemaker
Therapy should not be delayed for patients with implanted pacemakers and a defibrillation attempt should be made if the patient is unconscious and not breathing. The AED has pacemaker detection and rejection; however, with some pacemakers the AED may not advise a defibrillation shock[1].

Placing Pads:
- Do not place the pads directly over an implanted device.
- Place the pad at least one inch from any implanted device.

CAUTION: Moving the Patient During a Rescue
During a rescue attempt, excessive jostling or moving of the patient may cause AEDs to improperly analyze the patient's cardiac rhythm. Stop all motion or vibration before attempting a rescue.

CAUTION: Systems Statement
Equipment connected to the analog and digital interfaces must be certified to the respective IEC Standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Anybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible that the system complies with the requirements of the system standard IEC 60601-1-1.

CAUTION: Case Cleaning Solutions
When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or a glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

CAUTION: The AED is programmed with software that has been tested to work with versions of ServiceLink and RescueLink that are included with the AED. When using older version of ServiceLink and RescueLink are used to communicate with this AED, there may be features described in this manual that are not available to be used. Also, when communicating with an older AED with the version of ServiceLink and RescueLink included with this new AED there may be features described in this manual that cannot be edited. The software in most cases will give an error message when incompatibilities occur.

[1] Cummins, R., ed., Advanced Cardiac Life Support; AHA (1994): Ch. 4.

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SYMBOL DESCRIPTIONS

The following symbols may appear in this manual, on the AED, or on its optional components. Some of the symbols represent standards and compliances associated with the AED and its use.

Dangerous Voltage: The defibrillator output has high voltage and can present a shock hazard. Please read and understand all safety alerts in this manual before attempting to operate the AED.

Attention!: Identifies important information in this manual, on the AED, or on its component parts regarding the safe and proper use of the AED.

Defibrillator Proof Type BF Equipment: The AED, when connected to the patient's chest by the pads, can withstand the effects of an externally applied defibrillation shock.

CE Mark: This equipment conforms to essential requirements of the Medical Device Directive 93/42/EEC.

0086

IP24 The AED is protected against the effects of splashing water in accordance with IEC 60529.

Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, EN60601-1 and EN60601-2-4. Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.

International symbol for ON. Open the lid to turn on the AED.

Open the lid to turn ON the AED.

Indicates the AED battery status. The illuminated areas indicate the remaining battery capacity.

Indicates AED requires maintenance by authorized service personnel.

When the **SHOCK** indicator is lit, push this button to deliver a defibrillation shock.

The Z-bar provides a relative visual indicator of the total transthoracic impedance between the two defibrillation pads.

A red indicator with a BLACK X means the Responder AED Pro requires operator attention or maintenance, and is not RescueReady. This symbol will be referred to as **RED** in the remainder of this manual.

A green indicator without a BLACK X means the Responder AED Pro is RescueReady. This symbol will be referred to as **GREEN** in the remainder of this manual.

Use pads by this date; install battery by this date.

Date of manufacture.

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Date of factory recertification (R)

Latex Free.

Disposable. Single patient use only.

Tear here to open.

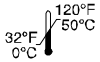
Do not recharge battery.

Position of pads on the chest of patient.
If flashing, check pads. The pads are missing, not connected or have compromised functionality.

Dispose of properly in accordance with all state, province, and country regulations.

Do not incinerate or expose to open flame.

Explosion Hazard: Do not use in the presence of a flammable gas, including Concentrated oxygen.



Upper and lower temperature limits.

Device Model Number. Battery Model Number.

Serial Number

Lot Number

Revision

Default start-up screen

Lithium Sulfur Dioxide

Lithium Ion

Additional information is provided in the AED Pro Operator's Manual.

Points to important information regarding the use of the AED.

Lift Here

Manufacturer

Authorized European Representative

Indicates placement of ECG leads and electrodes.

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Symbol for the marking of electrical and electronic equipment that must be recycled.

Fragile; handle with care

Keep away from rain. (Keep dry)

This way up

Stacking limit by number

General symbol for recovery/recyclable

Humidity Limitations

Atmospheric Pressure Limitations

In November 2005, the American Heart Association (AHA) and European Resuscitation Council (ERC) released new guidelines for CPR and defibrillation. This symbol indicates that the AED contains the new AHA/ERC guidelines for CPR and defibrillation.

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SECTION 2 - INTRODUCTION

OVERVIEW

This section presents information about the AED, its use, and the training requirements for operation.

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AED DESCRIPTION

The AED is a self-testing, battery-operated automated external defibrillator (AED). After applying the AED's pads to the patient's chest, the AED automatically analyzes the patient's electrocardiogram (ECG) and advises the operator to push the button and deliver a shock if needed. The AED uses one button and guides the operator through the rescue using a combination of voice prompts, audible alerts, and visible indicators. At the discretion of Advanced Life Support (ALS) personnel, the AED can be converted to manual override mode, and deliver a shock by pushing the SHOCK button. The AED can also provide non-diagnostic ECG monitoring.

INDICATIONS FOR USE / INTENDED USE

The AED with STAR Biphasic Waveform is intended to be used by personnel who have been trained in its operation. The operator should be qualified by training in basic life support, CPR/AED or other physician-authorized emergency medical response. The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest that are unresponsive and not breathing. If the victim is breathing post-resuscitation, the AED should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver therapy; or when in manual override mode, ALS personnel will monitor the ECG display and deliver a shock by pushing the shock button to deliver therapy.

WARNING: When the patient is a child or infant under 8 years of age or weighs less than 55 lbs (25kg), the AED should be used with the Model 9730 Pediatric Attenuated Defibrillation Electrode Pads. Therapy should not be delayed to determine the patient's exact age or weight.

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RHYTHMX® AED ECG ANALYSIS ALGORHITHM

The RhythmX AED ECG analysis algorithm provides superior ECG detection capabilities, allowing it to be placed on patients at risk for sudden cardiac arrest. The features available with the AED include the following:

- Detection Rate
- Asystole Threshold
- Noise Detection
- Non-Committed Shock
- Synchronized Shock
- Pacemaker Pulse Rejection
- SVT Discriminators
- Supraventricular Tachycardia (SVT) Rate

DETECTION RATE

All ventricular fibrillation (VF) and ventricular tachycardia (VT) rhythms at or above this rate will be classified as shockable. All rhythms below this rate will be classified as non-shockable. This rate is configurable between 120 bpm (beats per minute) and 240 bpm. Service can change this rate using the ServiceLink software. The default Detection Rate is 160 bpm. The Responder AED Pro detection rate is 160 bpm.

ASYSTOLE THRESHOLD

The Asystole baseline-to-peak threshold is set at 0.08 mV. ECG rhythms at or below 0.08 mV will be classified as Asystole and will not be shockable.

NOISE DETECTION

The AED will detect noise artifact in the ECG. Noise could be introduced by excessive moving of the patient or electronic noise from external sources like cellular and radiotelephones. When noise is detected, the AED will issue the prompt “ANALYSIS INTERRUPTED. STOP PATIENT MOTION” to warn the operator. The AED will then proceed to reanalyze the rhythm and continue with the rescue.

NON-COMMITTED SHOCK

After the AED advises a shock, it continues to monitor the patient ECG rhythm. If the patient’s rhythm changes to a non-shockable rhythm before the actual shock is delivered, the AED will advise that the rhythm has changed and issue the prompt “RHYTHM CHANGED. SHOCK CANCELLED.” The AED will enter CPR mode and prompt, “START CPR”.

SYNCHRONIZED SHOCK

The AED is designed to synchronize shock delivery on the R-wave. The AED will automatically attempt to synchronize to the R-wave. If delivery cannot be synchronized within one second, a non-synchronized shock will be delivered.

PACEMAKER PULSE DETECTION

The AED contains pacemaker pulse detection circuitry to detect pulses from an implanted pacemaker.

SVT (Superventricular Tachycardia) DISCRIMINATORS

The Responder AED Pro is supplied with the SVT Discriminator enabled and with the default setting "NO THERAPY FOR SVT". With the factory default setting of "NO THERAPY FOR SVT", the Responder AED Pro will not shock an SVT rhythm.

SVT Discriminators are sophisticated filters that analyze the morphology of the ECG waveforms and distinguish VF/VT from SVT and Normal Sinus Rhythms (NSR). The SVT Discriminator will only be applied to rhythms that fall between the Detection Rate and the SVT Rate. The factory default setting for this feature is "NO THERAPY FOR SVT", however Service can change the settings for this feature using the ServiceLink software.

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SVT RATE

All rhythms with rates between the Detection Rate and SVT Rate will be screened through a number of SVT Discriminators to classify them into VF/VT or SVT. Rhythms classified as SVT between the two set rates are not shockable. All SVT rhythms above the rates will be classified as shockable. The SVT Rate must be greater than the Detection Rate and is selectable by Service between 160 and 300 bpm or, “NO THERAPY FOR SVT” can be selected by Service using the ServiceLink software.

RESCUE PROTOCOL

The AED rescue protocol is consistent with the guidelines recommended by the American Heart Association (AHA)[1] European Resuscitation Council (ERC) and the International Liaison Committee on Resuscitation (ILCOR).

Upon detecting a shockable cardiac rhythm, the AED advises the operator to press the SHOCK button to deliver a shock and then advises the operator to start CPR.

Note: The standard CPR protocol of 120 seconds can be modified from 60 to 180 seconds in ServiceLink

OPERATOR TRAINING REQUIREMENTS

Persons authorized to operate the AED must have all of the following minimum training.

- Defibrillation training and other training as required by state, province, or country regulations.
- Training on operation and use of the AED.
- Additional training as required by the physician or Medical Director.
- A thorough understanding of the procedures in this manual.

Note: Keep valid certificates of training and certification as required by state, province, or country regulations.

[1]“Guidelines 2005 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care” American Heart Association; Circulation Vol112,Issue 24 Suppl. Dec 13, 2005

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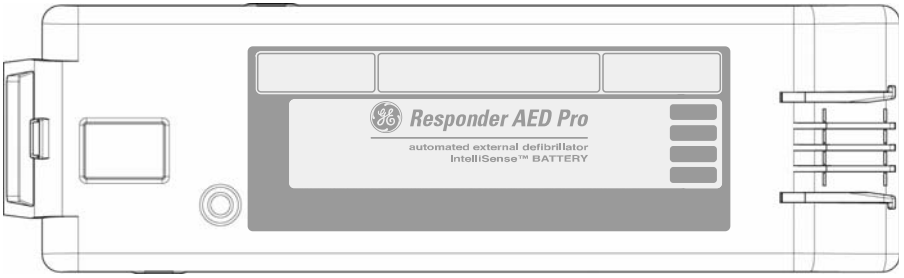
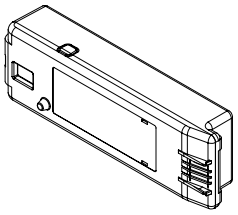
INTELLISENSE® Battery



The Responder AED PRO IntelliSense battery technology offers you the most advanced battery capabilities available for defibrillators. Responder AED Pro IntelliSense batteries contain an integrated memory chip that automatically stores important usage information, enabling the battery to maintain a complete history of its operating life. The actual battery history can be reviewed using the RescueLink software.
This history includes:



- Battery Identification
- Battery Type
- Original Date of Installation in an AED
- Number of Charges completed
- Time in Operation (hours: minutes)
- Days of Standby Operation
- Battery Capacity Remaining

BATTERY OPERATING LIFE

The battery operating life depends on the type of battery**,** actual usage and environmental factors.

The following table represents the expected life of the Responder AED Pro when used in Standby Mode.

Model	Estimated Shelf Life	Typical Shocks
2023681 (9145) Lithium	5 Years	Up to 290 shocks

BATTERY SHELF LIFE

The Responder AED Pro batteries have a shelf-life of five years. Shelf-life is defined as the length of time a battery can be stored, prior to installation into AED, without degrading its performance.

Note: Storing the battery outside its specific range (0-50°C) will decrease battery life.

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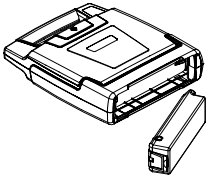
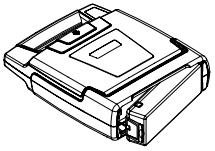
BATTERY INSTALLATION



1. With the label on the battery facing the AED battery compartment, insert the battery as shown in the drawing.



2. Push the latched end of the battery firmly into the AED, as shown in the drawing, until the battery snaps into place. The exposed side of the battery should be flush with the outside of the AED case.

3. Open the lid for 5 seconds to initiate self-test. If the battery is installed properly, the STATUS INDICATOR will turn GREEN. Close the lid.

WARNING: Battery Model 2023681-001 is Not Rechargeable
Do not attempt to recharge the battery. Any attempt to recharge the battery may result in an explosion or fire hazard.

CAUTION: Lithium Sulfur Dioxide Battery
Pressurized contents: Never recharge, short circuit, puncture, deform, or expose to temperatures above 65°C (149°F). Remove the battery when discharged.

CAUTION: Battery Disposal
Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

CAUTION: Use only General Electric Approved Equipment
Using batteries, pads, cables, or optional equipment other than those approved by General Electric may cause the Responder AED Pro to function improperly during a rescue.

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RECHARGEABLE BATTERY

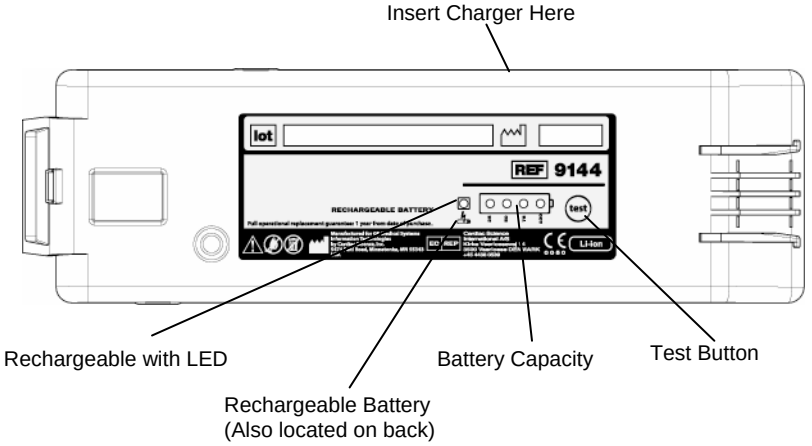
The rechargeable battery (P/N 2023489-001) and charger (P/N 2023490-001) are separately sold accessories for the Responder AED PRO.

DIRECTIONS FOR USE:

- Remove the rechargeable battery from the Responder AED PRO; the rechargeable battery can only be recharged when removed from the Responder AED PRO.
- Plug the charger into an appropriate electrical outlet.
- Insert the charger cable into the rechargeable battery and ensure the yellow LED above the rechargeable battery symbol is on. Charging is complete when the yellow Charge LED goes out, and the four green Fuel Gauge LEDs are continuously lit.
- Remove the charger cable from the battery when done charging. Charging may be terminated early by removing the charger cable from the battery. If the battery is charged for a minimum of 3 hours, the stated capacities will be met.

Model	Estimated Shelf Life	Warranty	Typical Shocks
2023681 Lithium Sulfur Dioxide	5 Years	1 Year of 12 hours of use, whichever occurs first	Up to 290 shocks

If the yellow Charge LED blinks continuously, a charging error has occurred. Contact customer service in the event of a charging error.



CAUTION: Use only Approved Equipment
The Rechargeable battery is made solely for Powerheart AED G3 Pro, and is NOT to be used with any other AED models. Using batteries, pads, cables, or optional equipment other than those approved by the manufacturer may cause the AED to function improperly during a rescue.

CAUTION: Lithium-ion Battery
Never short circuit, puncture, deform, or expose to temperatures above 65°C (149°F).

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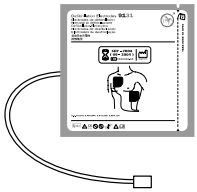
DEFIBRILLATION ELECTRODES (PADS)



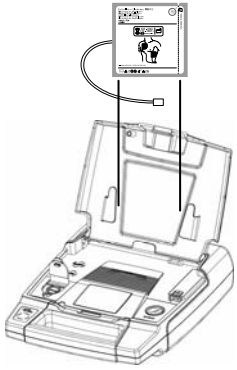
The defibrillation pads come in a ready-to-use, sealed package containing one pair of self-adhesive pads with an attached cable and connector. The pads are disposable and should be discarded after each rescue. The pads have a limited shelf life and shall not be used beyond the expiration date. Keep a fresh, unopened pair of pads plugged into the AED at all times. Refer to the pad package label for operation temperatures.

On the Responder AED PRO, an audible and visual alert will indicate after the self-test if the pads are missing, unplugged or damaged.

CAUTION: Possible Improper AED Performance

Using pads that are damaged or expired may result in improper AED performance.

PAD INSTALLATION



1. Open the lid of the AED.
2. Place the package into the lid so that the expiration label is visible through the clear window on the lid. The expiration date of the pads will then be readable without opening the lid of the AED.
3. Match the color of the connectors (red to red), slightly lift the tab of the pad socket and then plug the pad connector into the AED case as shown in the drawing.
4. Tuck the excess cable length in the bottom holder as shown in the drawing. With the package completely secured to the AED lid, close the lid.
5. Make sure the expiration date is visible through the clear window of the lid.
   Make sure that the **STATUS INDICATOR** is **GREEN**.

CAUTION: Use only Approved Equipment
Using batteries, pads, cables, or optional equipment other than those approved by General Electric may cause the AED to function improperly during a rescue.

CAUTION: Possible Improper AED Performance
Using pads that are damaged or expired may result in improper AED performance.

DIRECTIONS FOR USE:

1. Do NOT open until ready to use, short term use only.
2. Ensure the skin site is clean and dry.
3. Separate one pad from liner.
4. Place one pad on skin in either location.
5. Peel and place remaining pad.

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AED INDICATORS

The following indicators are located on the AED.

RESCUEREADY® STATUS INDICATOR

The **STATUS INDICATOR** is located on the AED handle. When this indicator is **GREEN**, the device is RescueReady. This means the Responder AED Pro self-tests have verified the following:

- Battery has an adequate charge.
- Pads are properly connected to the Responder AED Pro and in working order.
- Integrity of the internal circuitry is good.

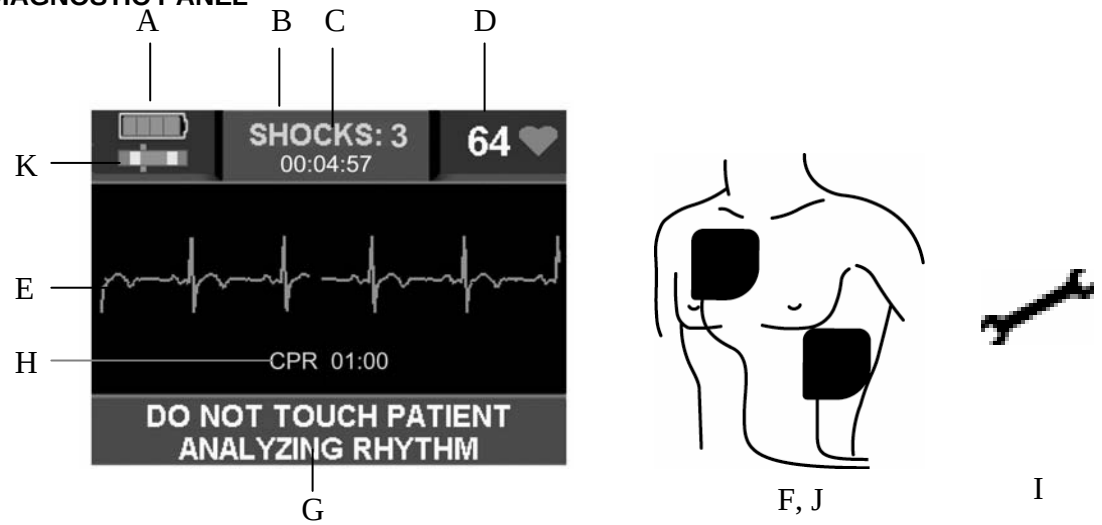
When the **STATUS INDICATOR** is **RED**, maintenance is required.

Note: When Status Indicator is RED or Service Indicator is illuminated, device cannot be used to perform a rescue.

AUDIBLE MAINTENANCE INDICATOR

When the daily, weekly or monthly self-test determines service is required, an audible beep is sounded every 30 seconds until the lid is opened or the battery power is depleted. Opening and closing the lid may deactivate the beep. If the error is not corrected by the next automatic self-test, the beep will be reactivated.

DIAGNOSTIC PANEL



A. SMARTGAUGE BATTERY Indicator

This indicator displays the battery capacity. At maximum charge, the battery is GREEN. With use, the GREEN level will gradually go out from right to left as the battery capacity decreases. Once the battery level is depleted, the battery indicator will turn to RED and flash, and the battery should be replaced.

Note: When the battery indicator is initially RED – upon lid opening or at any time during a rescue – a “BATTERY LOW” prompt will be issued at once. However, the AED is capable of delivering at least nine more defibrillation shocks after the first time a “BATTERY LOW” prompt is issued.

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B. NUMBER OF SHOCKS DELIVERED Indicator
This indicator counts and displays the number of shocks delivered.

C. ELAPSED RESCUE TIME Indicator
This indicator times and displays the elapsed rescue time.

Note: There is a 3 second delay between the time the AED lid is opened and the start of the rescue (when the lid was first opened).

D. HEART RATE Indicator
This indicator displays the patient's heart rate.

E. ECG Display
Four and a half seconds of the patient's ECG is displayed.

F. PAD PLACEMENT Display
Visually assists the rescue with pad placement with the directions for use. Appropriate text prompts are also displayed.

G. TEXT Display
The text display has 2 lines of text. It provides the operator with information regarding system initialization, text version of the voice prompts and data during a rescue, and diagnostics.

System initialization occurs when the lid is first opened. The text display shows the operator the identifiers for the internal code, voice prompts and text prompts versions.

H. CPR Counter
During CPR, a countdown timer will be displayed.

I. SERVICE Indicator
When apparent, indicates that service is required that can only be performed by qualified service personnel.

Note: When Status Indicator is RED or Service Indicator is illuminated, device cannot be used to perform a rescue.

J. PAD Indicator
When flashing with voice and text prompt indicating "Check Pads", indicates to check pads when pads are:

- Not properly connected to the AED
- Not within operational specifications (cold, dried, damaged)
- Disconnected from the patient during a rescue

K. Z-BAR Indicator
The Z-Bar provides a relative visual graphical indicator of the total transthoracic impedance between the two defibrillation pads. The Z-Bar is used in the assessment of:

- Adequate pad placement
- Pad quality and integrity
- Pad adhesion to the patient's skin
- Proper pad connection to the AED
- Provides for quick assessment between pad off and pads shorted

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CONTROL BUTTONS

The AED has two buttons.

SHOCK BUTTON

The SHOCK button is located at the far right of the control panel.
Delivers a defibrillation shock. The word SHOCK and the shock button indicator LED will illuminate RED when the AED is ready to deliver a defibrillation shock to the patient. Note modification to behavior below when in manual mode.

MANUAL OVERRIDE BUTTON

The MANUAL OVERRIDE button is located at the far left of the control panel and converts the device from automated mode to manual. This feature should only be used by ALS personnel.

MANUAL OVERRIDE

- Lift the cover to access the button.
- Converts to manual standby mode when pushed once, a voice prompt "*Press Manual Button Again to Confirm*", will be heard. Converts to manual mode when MANUAL button is pressed again.
- If the rescuer does not confirm within 30 seconds of the capacitors charging, the AED will revert back to AED Mode.
- If the Medical Director has disabled this feature in Servicelink, an icon indicating No MANUAL MODE will appear in the bottom left of the display.

REMAIN IN MANUAL MODE

This feature is intended for advanced medical personnel with the ability to differentiate between shockable and non-shockable cardiac rhythms. With Remain In Manual Mode enabled and the user enters manual mode, the AED will remain in the manual mode. Further AED rhythm analysis, and CPR prompting are disabled when "Remain in Manual Mode" is enabled.

SETTING THE AED INTERNAL CLOCK

The internal clock is preset at Central Standard Time and should be reset to the correct date and local time. The AED will automatically adjust itself for daylight savings time. This feature can be turned off using the ServiceLink software. To set the clock, you will need a PC with Windows 95 or later operating system, RescueLink software installed, an IR port on the PC, and an IR cable as specified below.

To set the clock settings:

- Open the lid and remove pads from the pads socket.
- Ensure that the PC is set at the correct local time and date.
- Point IR port on the AED to IR eye on the PC and select G3 Pro.
- Run the RescueLink software on the PC.
- Verify that the voice prompt states "Communications Mode".
- Click Communications on the main menu. Select AED Date and Time.
- Click on the Get button to review the current time in the AED.
- If the time and date is incorrect, click Set to set new time and date. The AED date and time will automatically be updated to the PC's time and date.
- Reinstall pads per instructions on page 19.
- Close the lid.

Note: The IR port on the AED is designed to work with IR cable ACT-IR220LN115 from ACTiSys Corp. on Windows based PCs only. Please contact customer service to order, P/N 162-0108-001. Other IR products may interfere with the transmission and are not for use with the AED.

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SECTION 3: MAINTENANCE & TROUBLESHOOTING

OVERVIEW

This section presents information about the AED diagnostics self-tests, maintenance, and service indications.

Topic	Page #
Self-Tests	21
Indicator Troubleshooting Table	22
Scheduled Maintenance	22
Authorized Repair Service	24
Defib Testing	24

SELF-TESTS

The AED has a comprehensive self-test system that automatically tests the electronics, battery, pads, and high voltage circuitry. Self-tests are also activated every time you open and close the AED lid.

These self-tests eliminate the need for in depth periodic / annual maintenance testing. The comprehensive self-tests insure that the Responder AED Pro is RescueReady®, with minimal user involvement and maintenance costs. Once a month during the daily self-tests, the AED performs a full charge of the capacitors. During this test the AED monitors the charge time, voltage level and proper discharge function. When the Responder AED Pro requires maintenance, audible and/or visual indicators are activated. By monitoring the visual and audible indicators, the user can be assured that the Responder AED Pro is ready to conduct a rescue.

When performing the self-tests, the AED completes the following steps automatically.

- Turns itself ON, and the **STATUS INDICATOR** changes to **RED**.
- Performs the self-test.
- If successful, the **STATUS INDICATOR** reverts to **GREEN**.
- Turns itself OFF if the lid is closed.

There are three types of automatic self-tests. The Daily Self-Test checks the battery, pads, and the electronic components. The Weekly Self-Test completes a partial charge of the high voltage electronics current in addition to the items tested in the Daily Self-Test. During the Monthly Self-Test, the high voltage electronics are charged to full energy.

Self-tests will be initiated upon opening the lid and again upon closing the lid. If the self-test detects an error, the **STATUS INDICATOR** will remain **RED**. Upon closing the lid, an audible alert will be issued. The Diagnostic Panel under the lid will indicate the source of the problem according to the Indicator Troubleshooting Guide Table on the next page.

CAUTION: Temperature/Humidity/Pressure Extremes
Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self test verifies the impact of extreme environmental conditions on the AED; if the daily self test determines environmental conditions outside of the AED's operating parameters, the "SERVICE REQUIRED" alarm will sound to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once. See Section 7 – Technical Data, Parameters, Operation and Standby Conditions.

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INDICATOR TROUBLESHOOTING TABLE

The following is a troubleshooting table for the AED indicators.

VIEW	SYMPTOM	SOLUTION
	Red **SERVICE** indicator (LED) is indicated on the screen.	Maintenance by authorized service personnel is required. Call Customer Service or your local distributor.
	Red **PADS** indicator (LED) is indicated on the screen.	Connect the pads or replace with a new pair.
	The **LAST BATTERY** indicator (LED) is red and flashing.	The battery is low. Replace with a new battery.
	STATUS INDICATOR is **RED**, and no other indicators on the diagnostic panel are lit.	The battery power is completely depleted. Replace with a new battery. If **STATUS INDICATOR** remains **RED**, refer to the Responder AED Pro for maintenance. Call Customer Service or your local distributor.

SCHEDULED MAINTENANCE

DAILY MAINTENANCE

Check the **STATUS INDICATOR** to ensure that it is **GREEN**. When the indicator is **GREEN**, the Responder AED Pro is ready for a rescue. If the indicator is **RED**, refer to the Troubleshooting Table in this chapter.

MONTHLY MAINTENANCE

1. Open the AED lid.
2. Wait for the AED to indicate status
3. Observe the change of the **STATUS INDICATOR** to **RED**. After less than 5 seconds, verify that the **STATUS INDICATOR** returns to **GREEN**.
4. Observe the expiration date on the pads.
5. Listen for the voice prompts.
6. Close the lid and confirm that **STATUS INDICATOR** remains **GREEN**.

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ANNUAL MAINTENANCE

Perform the following tests annually to confirm that the diagnostics are functioning properly and to verify the integrity of the case.

Check the Integrity of the Pads and Circuitry

1. Open the AED lid.
2. Remove the pads.
3. Close the lid.
4. Confirm that the **STATUS INDICATOR** turns **RED**.
5. Open the lid and confirm that the **PAD** indicator is lit.
6. Reconnect the pads and close the lid.
7. Make sure the expiration date is visible through the clear window of the lid.
8. Check to make sure that the **STATUS INDICATOR** is **GREEN**.
9. Open the lid and confirm that no diagnostic indicators are lit.
10. Check the expiration date of the pads; if expired, replace them.
11. Check the pad's packaging integrity.
12. Close the lid.

Check the Integrity of the Service Indicator (LED) and Circuitry

1. Immediately after opening the AED lid, press and hold the **SHOCK** button and confirm that the **SERVICE** LED is lit.
2. Release the **SHOCK** button.
3. Close the lid.
4. Verify that the **STATUS INDICATOR** remains **RED**.
5. Open the lid and confirm that no diagnostic indicators are lit.
6. Close the lid.
7. Verify the **STATUS INDICATOR** turns **GREEN**.

Check the Integrity of the Case

Examine the molded case of the AED for any visible signs of stress. If the case shows signs of stress, contact Customer Service or your local distributor.

Cleaning the AED Case

Gently clean the surface of the AED case with a damp sponge or with a cloth and mild soap.

CAUTION: Case Cleaning Solutions
When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or a glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

No periodic safety analysis tests referred to by the IEC 60601-1 international standard are required.

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AUTHORIZED REPAIR SERVICE

The AED has no user-serviceable internal components. Try to resolve any maintenance issues with the AED by using the Troubleshooting Table presented in this chapter. If you are unable to resolve the problem, contact Customer Service.

WARNING: Shock Hazard
Do not disassemble the AED! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to authorized service personnel.

Note: The warranty will be void upon unauthorized disassembly or service of the AED.

DEFIB TESTING

- **Required Equipment:** Dynatech-Nevada Impulse 3000 Defib Analyzer or equivalent
- **Method:**

Note: Detailed instructions for using the ServiceLink software can be found in the ServiceLink manual provided on the ServiceLink software CD.

1. Use ServiceLink to ensure the AED is set to a known protocol:

200VE	300VE	300VE
200VE	200VE	300VE
150VE	200VE	200VE
150VE	150VE	200VE
200VE	200VE	200VE

2. Set the defibrillator tester to output a Ventricular Fibrillation ECG.
3. Power on the AED.
4. Connect the AED defibrillator pads to the defibrillator tester.
5. The AED should automatically analyze and charge.
6. Press the Flashing shock button on the AED.
7. Record the energy delivered as displayed on the defibrillator analyzer.
8. Repeat for a total of three shocks.
9. Replace electrodes.
10. Close the lid and verify that the indicator turns green after approximately 5 seconds.

- **Acceptance Criteria:**

150VE Shock – Acceptable range is: 120J to 180J

200VE Shock – Acceptable range is: 170J to 230J

300VE Shock – Acceptable range is: 230J to 310J

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SECTION 4: TECHNICAL DATA

OVERVIEW

This section presents technical data about the AED.

Topic	Page #
Parameters	25
Safety and Performance Standards	28
STAR Biphasic Waveform	30
STAR Biphasic Energy Protocols for Responder AED PRO	32
RHYTHMx ECG analysis performance	33

PARAMETERS

OPERATION

Semi-Automatic (shock advisory)

AUDIBLE ALERTS

Voice Prompt
Maintenance Alert

VISIBLE INDICATORS
STATUS INDICATOR

Display Panel

BATTERY Indicator
NUMBER OF SHOCKS DELIVERED Indicator
ELAPSED RESCUE TIME Indicator
HEART RATE Indicator
ECG Display
PAD PLACEMENT Display, CHECK PADS indicator
TEXT Display
CPR Counter
SERVICE Indicator
Pad Indicator
Manual Mode Indicator
ECG Monitoring Mode Indicator
Z-BAR Indicator

RESCUE DATA STORAGE

Storage	Capacity
Internal	60 minutes ECG data with event annotation

DIMENSIONS

Measurement	Dimension
Height	8 cm (3.3 in)
Width	27 cm (10.6 in)
Depth	31 cm (12.4 in)

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WEIGHT

Model	Weight with Batteries and Pads
9300	3.20 kg (7.0 lb)

ENVIRONMENTAL OPERATION AND STANDBY CONDITIONS

Atmosphere	Condition
Temperature	0°C to 50°C (32°F to 122°F)
Humidity	5% to 95% (non-condensing)
Pressure	57kPa (4,572m / +15,000ft) to 103kPa (-152m / -500ft)

SHIPMENT AND TRANSPORT ENVIRONMENTAL CONDITIONS (for up to 1 week)

Atmosphere	Condition
Temperature	-30°C to 65°C (-22°F to 149°F)
Humidity	5% to 95% (non-condensing)
Pressure	57kPa (4,572m / +15,000ft) to 103kPa (-152m / -500ft)

PADS

- Self-adhesive, disposable defibrillation pads
- Minimum combined surface area: 228cm2
- Extended length of lead wire: 1.3m

LITHIUM BATTERY SPECIFICATIONS

- Output voltage: 12VDC (max)
- Batteries are non-rechargeable
- Lithium contents: 9.2g (max)
- Check local regulations for disposal information

Model	Estimated Shelf Life	Typical Shocks
2023681 Lithium	5 Years	Up to 290 shocks

The battery operating life depends on the type of battery, actual usage and environmental factors.

RECHARGEABLE BATTERY SPECIFICATIONS

- Battery Voltage: 11.1V
- Chemistry: Lithium-ion. Refer to local regulations.
- Compatibility: Responder AED Pro Model 2023440
- Battery Capacity: 60 shocks minimum (100 shocks typical) or 3 hours minimum (6 hours typical) of ECG display time.
- Battery Charge Time: 3 hours for stated capacity, 4.5 hours to fully charge completely depleted battery.
- Battery Standby: 6 months
- Battery Life: 2.5 years or 300 Battery charge-discharge cycles, whichever comes first.
- Battery Weight: 1 lb. 3 oz

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BATTERY CHARGER

- Power Requirements: 90 to 132 VAC or 198 to 264 VAC at 47 to 63 Hz

The Charger operates from, and accepts standard IEC mains power cables.
It is recommended that you keep a spare, non-rechargeable battery nearby.

BATTERIES AND CAPACITOR CHARGE TIMES

A new battery typically takes 10 seconds to charge the AED to maximum energy.

A battery with reduced capacity causes the red LED light to initially turn ON and typically takes 13 seconds to charge a fully discharged AED to maximum energy.

The maximum time from “Power On” to “Ready to Shock” is 28 seconds for a new rescue.
The maximum time from “Analyze” to “Ready to Shock” is 22 seconds for a new rescue.

AED SELF-TEST SEQUENCE

Frequency of Self-Test	What is Tested?
Daily	Battery, pads, internal electronics, **SHOCK/CONTINUE** button, and software (no charge).
Weekly	Battery, pads, internal electronics, **SHOCK/CONTINUE** button, and software (partial charge).
Monthly (every 28 days)	Battery under load, pads, internal electronics, full-energy charge cycle, **SHOCK/CONTINUE** button, and software (full charge).
Open Lid (when lid is opened)	Battery, pads, internal electronics, **SHOCK/CONTINUE** button, and software.
Close Lid (when lid is closed)	Battery, pads, internal electronics, **SHOCK/CONTINUE** button, and software.

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SAFETY AND PERFORMANCE STANDARDS

AED MODEL 2023440

The AED has been designed and manufactured to conform to the highest standards of safety and performance including electromagnetic compatibility (EMC). The Responder AED Pro Model 2023440 and pads conform to the applicable requirements of the following:

CE
CE Marked by BSI 0086 per the Medical Device Directive 93/42/EEC of European Union

ETL
Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, EN60601-1 and EN60601-2-4. Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.

Electrical, Construction, Safety and Performance
IEC 60601-1 (1998), Amendments 1 (1991) & 2 (1995)
IEC 60601-2-4 (2002)
IEC 60601-1-4 (2000)
ANSI/AAMI DF-39 (1993)

Electromagnetic Compatibility (EMC)
IEC 60601-1-2 (2001)
IEC 60601-2-4 Section 36
ANSI/AAMI DF-39(1993) Section 3.3.21

The unit is safe for human use in compliance with the IEC 60601-1 Safety Analysis Tests standard.

EMMISIONS

Field	Standard or Compliance
E-M	IEC 55011/CISPR 11, Group 1, Class B
Magnetic	ANSI/AAMI DF39, <0.5mT on surface, except for within 5cm of the lid magnet and the speaker

IMMUNITY

Field	Standard or Compliance
E-M	IEC 61000-4-3, Level X, (20V/m) IEC 60601-2-4, Section 36.202.3 (20-V/m) AAMI DF39, Section 3.3.21.2.1
Magnetic	IEC 61000-4-8 (2001) IEC 60601-2-4 (2002), Section 36.202.8 AAMI DF39, Section 3.3.21.2.3 80A/m, 47.5Hz – 1,320Hz
ESD	IEC 61000-4-2, Level 3 IEC 60601-2-4 (2002), Section 36.202.2 6KV contact discharge, 8KV air gap discharge

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ENVIRONMENTAL CONDITIONS

Field	Standard or Compliance
Free Fall Drop	IEC 60068-2-32 (1975) AM 2 (1990), 1 meter
Bump	IEC 60068-2-29 (1987), 40g and 6000 bumps
Vibration (Random)	IEC 60068-2-64 (1993): 10Hz –2KHz, 0.005 – 0.0012 g2/Hz
Vibration (Sine)	IEC 60068-2-6 (1995): 10Hz – 60Hz, 0.15 mm and 60Hz – 150 Hz, 2g
Enclosure Protection	IEC 60529 (2001), IP24

SHIPPING AND TRANSPORT CONDITIONS

ISTA Procedure 2A

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STAR BIPHASIC WAVEFORM

The STAR Biphasic Waveform is designed to measure the patient's impedance and deliver a customized shock. This allows the delivery of an optimized energy level to each patient. The energy levels for the Responder AED Pro are available in three on next page for additional information.

The waveform generated by the Responder AED Pro is a BIPHASIC TRUNCATED EXPONENTIAL waveform that is compliant with ANSI/AAMI DF2 and DF39. The following is a graph of the waveform voltage as a function of time when the AED is connected to a 50-Ohm resistive load. (See figure A1 and Tables A1through A3)

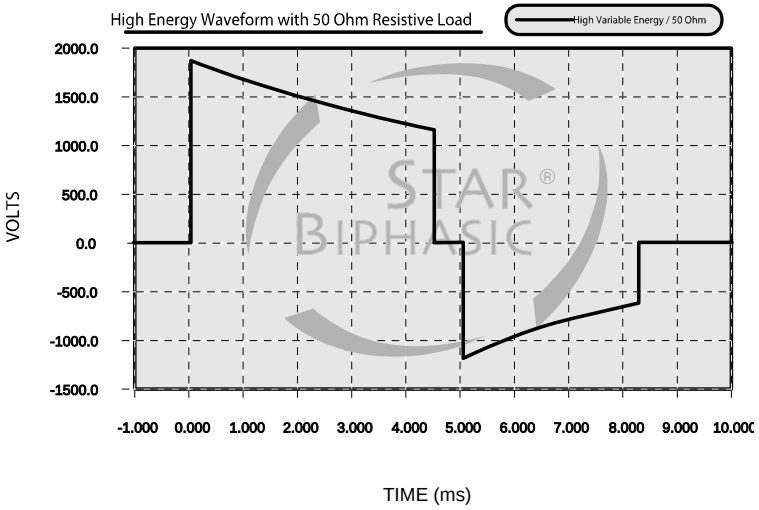

Figure A1. STAR BIPHASIC WAVEFORM

Table A1 - Ultra-Low Current Responder AED Pro (all values are typical)

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	Voltage (Volts)	Duration (ms)	Voltage (Volts)	Duration (ms)	Energy (Joules)
25	1390	3.3	730	3.2	145-195
50	1420	4.5	915	3.2	130-175
75	1430	5.8	980	3.2	120-160
100	1435	7.0	1020	3.2	110-150
125	1440	8.3	1040	3.2	105-140

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Table A2 – Low Variable Energy Waveform Responder AED Pro (all values are typical

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	Voltage (Volts)	Duration (ms)	Voltage (Volts)	Duration (ms)	Energy (Joules)
25	1570	3.3	825	3.2	200-250
50	1600	4.5	1030	3.2	170-210
75	1610	5.8	1105	3.2	120-160
100	1615	7.0	1150	3.2	150-180
125	1620	8.3	1170	3.2	140-170

Table A3 – High Variable Energy Waveform Responder AED Pro (all values are typical

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	Voltage (Volts)	Duration (ms)	Voltage (Volts)	Duration (ms)	Energy (Joules)
25	1885	3.3	990	3.2	265-360
50	1920	4.5	1240	3.2	235-320
75	1930	5.8	1325	3.2	215-295
100	1940	7.0	1380	3.2	200-270
125	1945	8.3	1405	3.2	190-260

ENERGY LEVELS AND PATIENT IMPEDIANCE

The Biphasic Truncated Exponential (BTE) waveform utilizes variable energy. The actual energy delivered will vary with the patient's impedance and the device will deliver a shock when impedance is between 25-180 Ohms. Energy will be delivered at three different levels referred to as ultra-low variable energy, low variable energy, and high variable energy as shown in the above waveform tables.

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STAR BIPHASIC RESCUE PROTOCOLS FOR RESPONDER AED Pro

The patented STAR® Biphasic defibrillation waveform will deliver variable escalating energy that is customized to each patient's needs based upon a patient's thoracic impedance. This customization adjusts for the unique physical differences between patients. The range of impedance over which the device will deliver a shock is 25-180 Ohms. The Responder AED Pro comes equipped with five different FDA-cleared biphasic rescue protocols.

The operator, with guidance, direction and implementation from its designated AED program Medical Director, may select from one of these five protocols when placing the into service. The AED's factory default rescue protocol is 200-300-300 Joule (J) escalating Variable Energy (VE). The first shock is delivered within the range of 140J-250J (200J nominal). Subsequent shocks are delivered within a range of 190J-360J (300J nominal).

These protocols are selected by using our ServiceLink software program. The five biphasic energy protocols available are as follows:

Rescue Protocols	Shock Sequence[1]	Energy Level	Energy Range (J)
Factory Default	1.	200VE	140J-250J
	2.	300VE	190J-360J
	3.	300VE	190J-360J
Protocol #2	1.	200VE	140J-250J
	2.	200VE	140J-250J
	3.	300VE	190J-360J
Protocol #3	1.	150VE	105J-195J
	2.	200VE	140J-250J
	3.	200VE	140J-250J
Protocol #4	1.	150VE	105J-195J
	2.	150VE	105J-195J
	3.	200VE	140J-250J
Protocol #5	1.	200VE	140J-250J
	2.	200VE	140J-250J
	3.	200VE	140J-250J

[1] The ultra-low current, low current and high current shocks are variable energy. The actual energy is determined by the patient's impedance.

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RHYTHMX ECG ANALYSIS PERFORMANCE

The AED RHYTHMx ECG Analysis system analyzes the patient's ECG and advises you when the AED detects a shockable or non-shockable rhythm.

This system makes it possible for a person, with no training in the interpretation of ECG rhythms, to offer defibrillation therapy to victims of sudden cardiac arrest.

CARDIAC RHYTHMS USED TO TEST THE RHYTHM RECOGNITION DETECTION SYSTEM FOR CARDIAC SCIENCE AED

Rhythm Class	Specifications
Shockable Rhythm – VF	Meets AAMI DF 39 requirement and AHA recommendation of Sensitivity of >90%
Shockable Rhythm – VT	Meets AAMI DF 39 requirement and AHA recommendation of Sensitivity of >75%
Non-Shockable Rhythm – NSR	Meets AAMI DF 39 requirement (>95%) and AHA recommendation (>99%) of Specificity
Non-Shockable – Asystole	Meets AAMI DF 39 requirement and AHA recommendation of Specificity of >95%
Non-Shockable– all other rhythms	Meets AAMI DF 39 requirement and AHA recommendation of Specificity of >95%

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Responder AED Pro

automated external defibrillator